UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/841,132	04/23/2001	Ajay Bhatia	210121.469C8	5589

500 7590 10/04/2002

SEED INTELLECTUAL PROPERTY LAW GROUP PLLC
701 FIFTH AVE
SUITE 6300
SEATTLE, WA 98104-7092

EXAMINER
LI, QIAN J

ART UNIT	PAPER NUMBER
1632	11

DATE MAILED: 10/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/841,132	BHATIA ET AL.	
	Examiner	Art Unit	
	Janice Li	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 July 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11 and 15-22* is/are pending in the application.

4a) Of the above claim(s) *1-11 and 15-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *detailed action* .

DETAILED ACTION

Election/Restrictions

Applicant's election of Group 124, drawn to a method of stimulating an immune response using a polypeptide, in Paper No. 10 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Per applicants' request, SEQ ID No: 190, instead of SEQ ID No: 431, will be examined in this application. Claims 12-14 have been canceled. Claims 19-22 are newly submitted. Claims 1-11, and 15-22 are pending in the application, however, claims 1-11 and 15-18 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 10.

Claims 19-22 are under current examination.

Priority

This application claims the benefit of the priority to multiple prior U.S. patent applications, however, the amino sequence SEQ ID No. 190 was first disclosed in the U.S. application 09/454,284, therefore, the priority date for the present application has been established as December 3, 1999.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for stimulating an immune response to the polypeptide SEQ ID NO: 190 in a subject, does not reasonably provide enablement for stimulating a protective immune response of said polypeptide in said subject. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

These claims are directed to a method for inducing an immune response against *Chlamydia* infection using a polypeptide comprising a sequence SEQ ID No: 190. Although claim 19 does not require a particular therapeutic use, the claims implicitly state the intended use of the method in light of the specification. With respect to claim breadth, the standard under 35 U.S.C. §112, first paragraph, entails the determination of what the claims recite and what the claims mean as a whole. When analyzing the enabled scope of the claims, the intended use is to be taken into account because the claims are to be given their broadest reasonable interpretation that is consistent with the specification. Accordingly, the claims are interpreted as a method for therapeutic use, to prevent, alleviate, treat, or cure a disease within an animal to which the substance is administered, therefore, will be evaluated by the standard. As such, the broadest

reasonable interpretation of the claimed invention properly encompasses protein vaccination for *Chlamydia* infection; therefore, the claims will be evaluated by that standard.

There are many factors to be considered when determining whether the disclosure satisfy the enablement requirements and whether undue experimentation would be required to make and use the claimed invention (see *In re Wands*, 858 F. 2d 731, 737, 8 USPQ 2d 1400, 1404, 1988). These factors include but are not limited to the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability of the art, the breadth of the claims, and amount of direction provided.

In view the guidance provided in the specification, the specification teaches that *Chlamydia* pmpG protein (SEQ ID NO: 190) could be recognized by T cells from patients with Chlamydia infection (Tab. VII), that Cap1 protein could trigger a protective immune response in mice (Example 9), however, the specification fails to teach whether pmpG polypeptide is capable of inducing a *protective* response against *Chlamydia* infection in any subject.

In view of the state of the art and the level of the skill, it is well known in the art of immunology that certain immune response to a pathogen may not be desirable in the host. In the case of Chlamydial infection, *Stagg* (Mol Med Today 1998 Apr;4:166-73) teaches, "BECAUSE PATHOLOGY IN SEVERE CHLAMYDIAL DISEASE IS IMMUNOLOGICALLY MEDIATED, THERE IS A DANGER THAT VACCINATION MIGHT PRIME AN INAPPROPRIATE IMMUNE RESPONSE AND INCREASE THE SEVERITY OF SUBSEQUENT DISEASE" (right column page 167). *Kim et al* (J Immunol 1999 Jun;162:6855-66) teaches "LITTLE IS KNOWN ABOUT WHETHER CHLAMYDIAL

GENITAL TRACT INFECTION IN HUMANS INDUCES ANY DEGREE OF PROTECTIVE IMMUNITY AGAINST REINFECTION. IF PROTECTIVE IMMUNITY DOES OCCUR, THE RELEVANT AG(S) AND IMMUNE MECHANISM(S) REMAIN TO BE DEFINED." (See page 6855, left column). They go on to teach past infections of humans with Ct may confer partial protection against subsequent infections, however, the induction of CTL responses in human *chlamydial* infection has not been reported, and their potential role in immune protection is unassessed (See page 6856, left column). Furthermore, they individually evaluate several major outer membrane proteins that would induce CTL in certain cells from different patients. They teach in the discussion that "APC UTILIZED IN STUDIES WITH MICE MIGHT HAVE RESULTED IN IMMUNOLOGICAL EVENTS THAT ARE DISTINCT FORM THOSE TRIGGERED BY APCS PRESENT IN HUMAN GENITAL TRACT", that ""NONE OF THESE STUDIES WITH MICE IDENTIFIED THE CT AGS RECOGNIZED BY PROTECTIVE CTLS." "FURTHER INVESTIGATIONS ARE NEEDED TO DEFINE MECHANISMS BY WHICH CTLS MIGHT PROTECT AGAINST CT AND TO EXAMINE WHETHER CTLS ARE IN PART RESPONSIBLE FOR IMMUNOPATHOLOGY". Moreover, another post-filing date art teaches that even though the Pmp proteins are highly immunogenic in post-abortion sheep sera, the role of these proteins in the progression of human infections remains to be determined (paragraph bridging left and right column of page 168, *Mygind et al,* FEMS Microbiol Let 2000;186:163-9). Thus, even though the specification discloses that pmpG protein of *Chlamydia* is recognized by T cells of infected individuals, it is insufficient to provide enablement for the polypeptide SEQ ID NO: 190 to induce a *protective* immune response. To enable a claim drawn to a protective immune response to a pathogen requires reduction to practice for improvement of the disease symptom, or the prevention of the re-infection in a subject to a subsequent challenge of pathogen. The

specification fails to provide an enabled disclosure commensurate to its scope as the claims encompass a protective immunity.

Thus, it is evident that at the time of the invention, one of the skill in the art, while acknowledging the significant potential of using *Chlamydia* proteins as a prophylactic and therapeutic composition, still recognized that the nature of the host immune response to pmp proteins is not fully elucidated, such therapy was neither routine nor accepted, and awaited significant development and guidance for its practice. Therefore, it is incumbent upon applicants to provide sufficient and enabling teachings within the specification for such therapeutic regimens.

According, it is concluded that based upon the nature of the claimed invention, the state of the art, the unpredictability found in the art, the teaching and working examples provided, and the breadth of the claims that it would require undue experimentation to practice the invention commensurate to its scope.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are vague and indefinite because claim 19 calls for stimulating an immune response, however, neither the subject of the stimulation nor the subject of the response have been identified in the claims.

The claims are vague and indefinite because claim 20 recites that the polypeptide of (b) is capable of stimulating T cells that are stimulated by SEQ ID No: 190. It is unclear whether stimulating T cells with SEQ ID No: 190 before the polypeptide (b) administration is a pre-requisition for the capability of the polypetide (b) in stimulating an immune response, thus, the metes and bounds of the claim is unclear.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 19-22 are rejected under 35 U.S.C. 102(a) as being anticipated by *WO 99/17741*.

Claims are drawn to a method of stimulating an immune response in a subject comprising administering to the subject a composition comprising an isolated polypeptide having a sequence 95% identical to the polypeptide of SEQ ID No: 190, wherein the composition further comprises a physiologically acceptable carrier and an adjuvant.

WO 99/17741 teach a polypeptide (fig. 3) having a sequence that is 97.2% identical to SEQ ID No: 190, and methods of using the polypeptide in a physiologically acceptable carrier for inducing a protective immune response in an animal (page 15, lines 3-15). *WO 99/17741* goes on to teach that adjuvants could be included in the composition to enhance the effectiveness of vaccination (page 20, lines 21-22). Therefore, *WO 99/17741* anticipate the instant claims.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Q. Janice Li whose telephone number is 703-308-7942. The examiner can normally be reached on 8:30 am - 5 p.m., Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah J. Reynolds can be reached on 703-305-4051. The fax numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of formal matters can be directed to the patent analyst, Dianiece Jacobs, whose telephone number is (703) 305-3388.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235. The faxing of such papers must conform to the notice published in the Official Gazette 1096 OG 30 (November 15, 1989).

Q. Janice Li
Examiner
Art Unit 1632

QJL
October 1, 2002

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER